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Horizon Scanning Technology Prioritising Summary

Anastomotic Devices for Coronary Surgery

June 2006



ASERNIP/S

**Australian
Safety
and Efficacy
Register
of New
Interventional
Procedures -
Surgical**



**Royal Australasian
College of Surgeons**

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Enquiries about the content of the report should be directed to:

HealthPACT Secretariat
Department of Health and Ageing
MDP 106
GPO Box 9848
Canberra ACT 2606
AUSTRALIA

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This Horizon scanning prioritising summary was prepared by staff from the Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S).

Name of Technologies:

The technologies included in this summary include:

- Symmetry Bypass Connector (St. Jude Medical Inc., St. Paul, MN, USA)
- Enclose II Anastomosis Assist Device (Novare Surgical Systems Inc., Cupertino, CA, USA)
- Spyder Device (Medtronic Inc., Minneapolis, MN, USA)
- PAS-Port Proximal Anastomosis System (Cardica Inc., Redwood City, CA, USA)
- C-Port Anastomosis System (Cardica Inc., Redwood City, CA, USA)
- Coronary Anastomotic Coupler (Converge Medical Inc., Sunnyvale, CA, USA)
- Magnetic Vascular Port (Ventrica Inc., Fremont, CA, USA)

Purpose and Target Group:

Anastomotic devices are designed to improve the safety of and promote better clinical results in patients undergoing coronary artery bypass graft (CABG) procedures. The aim of these devices is to reduce the possibility of potential adverse events during anastomosis creation, improve the ease of creation of anastomoses, reduce the time required for the creation of anastomoses and create consistent, repeatable quality anastomoses.

Anastomotic devices can be used in the creation of anastomoses in both on-pump (with cardiopulmonary bypass) and off-pump (beating heart) CABG procedures.

Impact Summary:

Background

Coronary artery disease, also called coronary heart disease, develops when atherosclerotic plaque builds up inside the walls of the coronary arteries that supply blood to the muscular tissue of the heart. Atherosclerotic build up results in narrowing of the affected coronary arteries. Significant narrowing of these arteries by 50% to 70% leads to insufficient supply of blood and oxygen to the heart muscle in the vicinity of the arteries, especially during times of stress and exercise (Heart Foundation 2004). This reduced blood flow leads to chest pain (angina) (Heart Foundation 2004). When narrowed arteries are completely blocked by a blood clot, the heart does not function properly and a heart attack ensues (Medtronic Inc. 2001).

Sufferers of coronary artery disease may be treated with a variety of therapies depending on the stage of the disease and the age of the patient including medications, angioplasty and stents (Medtronic Inc. 2001). However, in patients with advanced coronary artery disease, such as those with multi-vessel coronary artery disease, surgery remains the most effective treatment option (Medtronic Inc. 2001; Cardica Inc. 2006). CABG, is performed in patients with the aim of relieving angina, improving survival and improving the function of the heart

muscle by creating new routes around the narrowed or blocked arteries and restoring adequate blood flow (MedicineNet 2002).

During CABG surgery the surgeon cuts the sternum (breastbone) of the patient and opens up the chest (MedicineNet 2002). The procedure is performed either by stopping the heart and placing the patient on cardio-pulmonary bypass (on-pump CABG) or using stabilising devices to stabilise the section of the heart that requires the bypass graft (Medtronic Inc. 2001; MedicineNet 2002). The vessels most commonly used to create new routes around blocked coronary arteries are the long saphenous vein from the leg, the left internal mammary artery from the chest and the radial artery from the arm (Medtronic Inc. 2001). The graft technique involves sewing the graft to the native coronary artery past the point of blockage (distal anastomosis) and attaching the other end of the vein graft to the aorta (proximal anastomosis) (MedicineNet 2002). Hand-sewn anastomoses are considered the gold standard in CABG procedures because they provide excellent results, despite being technically demanding (Matschke *et al.* 2005; Carrel *et al.* 2004). However, despite being the 'gold standard' hand-sewn anastomoses still present risks and drawbacks. The surgeon's experience and skill as well as the patient's individual coronary anatomy and presence/progression of coronary disease are the most obvious potential causes of drawbacks and complications (Carrel *et al.* 2004). In addition, the variability between surgeons and procedures may affect the reproducibility of quality anastomosis and impact on risks.

Anastomosis devices used during CABG procedures can be classified into those which are used for the creation of an anastomosis between the aorta and the bypass graft (proximal anastomosis devices), and those which are used for the creation of an anastomosis between the bypass graft and the coronary artery (distal anastomosis devices) (Wolf 2005). This Prioritising Summary will evaluate the safety and efficacy of various recently developed anastomotic devices (proximal and distal) using the best currently available evidence.

Clinical Need and Burden of Disease

According to the Australian Heart Foundation, coronary artery disease, stroke and vascular disease are epidemic despite death rates falling in recent times, with approximately 3.67 million Australians affected (Heart Foundation 2004). Factors that increase the risk of developing these cardiovascular diseases include obesity, insufficient physical activity, high blood cholesterol, hypertension, smoking and excessive consumption of alcohol and diabetes (Heart Foundation 2004). In Australia, coronary artery disease is the country's biggest killer and was responsible for approximately 38% of all deaths in 2002 (Heart Foundation 2004).

CABG procedures were first performed during the 1960s and are now an established procedure (Davies and Senes 2003). However, CABG procedures are a treatment and not a cure for coronary artery disease (there is currently no cure for coronary artery disease), and repeat procedures are required for some patients (Davies and Senes 2003). Where the

procedure is successful, grafts may fail after 10 to 15 years, at which time further surgery or other interventions may be required (Davies and Senes 2003).

In 1999 there were 74 cardiac surgeons operating in 52 hospitals throughout Australia (Davies and Senes 2003). During the same period, approximately 17,321 coronary artery bypass graft procedures were performed, in addition to other cardiac procedures (Davies and Senes 2003). In a time where the health system is experiencing a shortage of health professionals across all areas it is imperative that optimal use of health resources is made. Given the ageing nature of the Australian population, more and more people will be at risk of developing coronary artery disease and as a result more will need treatment for coronary artery disease.

Estimated Cost Impact

In most circumstances, the costs of the anastomotic devices presented were not revealed by the searches conducted. Where costs information was available, this information is presented under the appropriate heading for each device.

The Medicare Benefits Schedule does not list any reimbursements for the use of any of the devices evaluated during CABG procedures. However, the reimbursement fees for CABG procedures range from \$1,722 to \$2067 depending on the number and type of grafts used (Item Numbers 38497, 38498, 38500, 38501, 38503, and 38504). From July 2004 to June 2005, a total of 5973 claims were made for these item numbers.

Proximal Anastomosis Devices

The creation of proximal anastomoses during CABG procedures poses several limitations. The most important of these is the interruption of blood flow to the aortic wall site where the anastomosis will be created. Conventionally this has been achieved with the use of totally or partially occluding clamps (Food and Drug Administration 2005; Wolf 2005). However in patients where atherosclerotic plaque is widespread and the number of areas suitable for anastomosis is limited, clamping of the aorta may not be a safe option as there is the potential for plaque and tissue fragments to become liberated and cause cerebral or distal organ emboli, leading to organ dysfunction (e.g. stroke, renal failure, or intestinal ischemia) (Food and Drug Administration 2005).

The designs of various proximal anastomosis devices enable these devices to potentially eliminate the requirement for partial or total clamps thus preventing any possible adverse events. In addition, by doing this they may also reduce the time required for the creation of anastomosis, thus reducing operation time and length of time a patient is under anaesthesia.

Four proximal anastomosis devices are presented.

Symmetry Bypass Connector (St. Jude Medical Inc., St. Paul, MN, USA)

The Symmetry Bypass Connector is a sutureless anastomosis device consisting of a nitinol connector, an aortic cutter and a delivery device (Eckstein *et al.* 2002). The device was originally designed to facilitate the attachment of a saphenous vein graft to the aorta without the requirement of aortic clamping during off-pump CABG procedures. In 2004, a Horizon Scanning Prioritising Summary by the National Horizon Scanning Unit documented the safety and efficacy of the device (Parella and Merlin 2004). While the summary revealed that the device was effective, concerns regarding the safety of the device were also raised. An update of the 2004 Horizon Scanning Prioritising Summary prepared in 2005 documented that voluntary discontinuance of the Symmetry device by the manufacturers in September 2004 (Parella *et al.* 2005). The Horizon Scanning Prioritising Summary also revealed that the device was subject of litigation in the United States (Parella *et al.* 2005). The Symmetry device has not been approved by the Therapeutic Goods Administration and is not available in Australia. For that reason no new data regarding the safety and efficacy of this device will be presented.

Enclose II Anastomosis Assist Device (Novare Surgical Systems, Cupertino, CA, USA)

The Enclose II system is a manual proximal anastomosis device designed to assist the creation of one to three proximal anastomoses during CABG procedures. In contrast to an automated proximal anastomosis device, the Enclose II device is not an integrated system that performs an aortotomy, delivers the graft to the aorta and creates the anastomosis. Instead, the Enclose II device provides appropriate space for conventional hand-sewn anastomoses by creating a dry area in the aortotomy without the need for any clamping of the aorta.

The Enclose device is composed of two parallel horizontal arms connected to a perpendicular plastic housing. The lower arm has an expandable diamond-shaped membrane which is controlled by a knob on the plastic housing, and sits in a fixed position. The upper arm is non-expandable and has a wire-form. It can be maneuvered up or down with a knob located at the top of the plastic housing. The back end of the lower arm is connected to a capped plastic tube which is itself connected to a metal bar inside the lower arm with two small holes that allow blood to flow back to the plastic tubing.

Before the device is inserted, the site of incision and up to three anastomotic sites are identified and marked. A purse-string suture is created at the incision site and a puncture is made. The lower arm of the device is then inserted and the device maneuvered to the site of the first anastomosis. A turn of a knob then opens the diamond-shaped membrane of the lower arm inside the aorta. Following this, the upper arm (outside the aorta) is lowered to create a watertight 1cm² area against the diamond-shaped membrane. Hemostasis is confirmed by opening the plastic tubing and allowing any excess blood to empty. The aortotomy can then be made and the proximal anastomosis created with a conventional hand-sewn method. Following anastomosis a bulldog clamp is placed on the graft vessel, the watertight seal released, and the device positioned for the next anastomosis. To remove the device, the watertight seal is released, diamond-shaped membrane retracted, the device removed from the aorta and purse suture tightened.

The Enclose II system is a third generation manual anastomotic device. Previous versions of the device include the Includer Vascular Clamp (first generation) and the Includer (Enclose) Vascular Clamp (second generation). All three versions of the device are very similar to each other and in various categories considered as identical by the US Food and Drug Administration Summary of Safety Information documents (K032589, K023682).

Stage of Development (in Australia):

- Experimental
- Investigational
- Nearly established

- Established
- Established but changed indication or modification of technique
- Should be taken out of use
- Not yet emerged in Australia

International Utilisation:

COUNTRY	LEVEL OF USE		
	Trials underway	Limited use	Widely diffused
United States		✓	
Europe		✓	
Australia			✓

Estimated Speed and Geographic and Practitioner Use Patterns of Diffusion in the Health System

The United States Food and Drug Administration (FDA) granted marketing approval for the Enclose II system in February 2004. The Enclose II system has also received the CE mark in Europe (date not revealed in searches). No listing for the Enclose II device was identified in the Australian Register of Therapeutic Goods during our searches. However, the device is currently being regularly used by surgeons throughout Australia (Dr. Benjamin Bidstrup, Personal Communication 2006).

Efficacy and Safety Issues

List of Studies Found

Total number of studies	3
Randomised controlled studies	1
Comparative studies	1
Case series studies	1

The current literature search identified three published studies evaluating the safety and efficacy of both the Enclose I and Enclose II devices. Because the difference between the Enclose I and II is minimal and does not substantially affect the function of the device, a study documenting the experience with the Enclose I device was included as well.

Akpinar *et al.* (2005) randomly assigned patients into two groups in order to compare the use of the Enclose II device (experimental group) to the standard side biting clamp with hand-sewn anastomosis (control group) in the creation of proximal anastomoses.

In the experimental group, the Enclose II device was used in 30 off-pump CABG procedures to create 49 proximal anastomoses. These included 25 vein, 10 free right internal thoracic artery and 14 radial artery connections to the aorta. In the control group, 32 proximal anastomoses were created including 25 vein, five radial artery and two free right internal thoracic artery connections to the aorta (Akpınar *et al.* 2005).

There were no adverse events related to the use of the Enclose II device or the side clamp reported.

Trans-cranial Doppler evaluation of the left and right middle cerebral arteries was performed during the creation of the proximal anastomoses in 26 patients in the experimental group and in 23 patients in the control group to measure trauma in terms of numbers of micro-emboli produced during the anastomotic procedure. The results demonstrated a significantly ($P < 0.05$) higher number of micro-embolic hits in patients in whom the conventional side-clamp method was used. Furthermore, in this group of patients a pattern of high micro-embolic hits at the time of aortic side-clamp removal was observed. No such patterns were observed in the Enclose II group. The results of this study suggest that in terms of trauma during the anastomosis procedure, the Enclose II device gives superior performance and results in the formation of less micro-emboli compared to the conventional method (Akpınar *et al.* 2005).

A case series study conducted by Aranki *et al.* (2005) evaluated the use of the Enclose I device in 50 patients. The investigators used the device under both on-pump (25 patients) and off-pump (25 patients) conditions to create a total of 76 proximal anastomoses. In the majority of these patients the left internal mammary artery was used as the graft vessel.

The outcome measures used to evaluate efficacy in this study consisted of time variables such as set-up time, and mean time for the creation of proximal anastomoses. Results of these variables indicated that the mean set-up time for the Enclose device in this study was 4.2 ± 1.40 minutes. Mean time for creation of the first proximal anastomosis was 8.3 ± 2.75 minutes and for the second anastomosis 7.1 ± 1.54 minutes. Unfortunately, there was no definition given for the term 'set-up' or 'creation of anastomosis'. It is therefore not known whether set-up includes full deployment of the system or whether creation is measured as the creation of the anastomoses by the hand-sewn method after device deployment.

Patency of the grafts was not an outcome measure in this study as the device is a manual anastomotic device. However, one patient underwent a postoperative angiogram for fear of possible complications. In this patient the Enclose mediated anastomosis was found to be patent.

Safety of the Enclose device was evaluated in terms of device related complications and technical failures. There were no adverse events related to the use of the device reported. Three technical failures were reported. All included rupturing of the lower membrane during the creation of the aortotomy after device deployment. In all cases this was corrected with the use of a new device.

In a comparative study conducted by Boova *et al.* (2006) 197 patients underwent off-pump coronary artery bypass surgery. Sixty patients (30.5%) received proximal anastomosis using the Enclose device while the remaining 137 (69.5%) patients received proximal anastomosis using the standard aortic-side-clamp technique. Patients received both proximal and distal anastomoses and a combination of both arterial and venous conduits were harvested to create the anastomoses. The Enclose group received 199 proximal and 406 distal anastomoses while the standard group received 107 proximal and 205 distal anastomoses. The main outcome measures of this study were stroke and death. Three patients who received the standard technique for the creation of anastomosis sustained permanent neurologic deficits following the surgery, compared to none in the Enclose group. Four deaths were reported (two in each group) although the cause of death was not stated. Two cases of device failure were also reported. In the first instance, conversion to conventional side-clamping was required and the anastomosis was constructed successfully. In the second instance, the anastomosis was also completed, however this was done using the device with impaired visibility. In both occasions the nature of the device failure was not reported.

The data obtained from the current literature suggest that the Enclose II may be a safe device to facilitate the construction of proximal anastomoses in both on-pump and off-pump procedures. Additionally the device has been demonstrated to be capable of producing proximal anastomoses using a variety of different graft vessels. When compared to the standard technique of the aortic side-clamp, use of the Enclose II device appears to be associated with fewer micro-embolic hits using trans-cranial Doppler evaluation.

The requirement for a minimum of two disease free sites to enable the creation of one anastomosis poses a limitation to the use of the device however.

Ethical Issues

No issues were identified from the retrieved literature.

Cultural or Religious Considerations

No issues were identified from the retrieved literature.

Other Issues

No issues were identified from the retrieved literature.

Recommendation:

Although the data presented is encouraging, there is a need for multi-center studies with larger numbers of patients to better demonstrate the true safety and effectiveness of the Enclose II device. Given the fact that the device is already in use in Australia and there is a

limited amount of evidence available on the Enclose device, it is recommended that the Enclose II Anastomosis Assist Device be monitored.

Horizon Scanning Report

Full Health Technology Assessment

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PAS-Port Proximal Anastomosis System (Cardica Inc., Redwood City, CA, USA)

The PAS-Port Proximal Anastomosis System is a fully automated device designed to facilitate the creation of anastomoses between a vein graft and the aorta during on-pump and off-pump CABG procedures without the need for aortic clamping. The PAS-Port system works by delivering a stainless steel implant that creates an anastomosis between the aorta and the graft vessel (Cardica 2006).

The PAS-Port system is contained in a package designed to facilitate the attachment of the graft vessel to the aorta whilst ensuring that the graft vessel is maintained moist and vital until deployment (Food and Drug Administration 2005). Deployment of the implant and anastomosis creation is facilitated by a delivery tool which creates the aortotomy and delivers the implant (to create the anastomosis) with one full turn of a knob. The implant itself has nine barbed, flanged tines which penetrate and securely capture the graft vessel. Prior to deployment, the graft vessel is attached to the implant while the implant is in a compressed state. On deployment, the implant expands and forms an inner and outer flange between the graft vessel and the aortotomy creating the anastomosis (Food and Drug Administration 2005).

Stage of Development (in Australia):

- Experimental
- Investigational
- Nearly established
- Established
- Established but changed indication or modification of technique
- Should be taken out of use
- Not yet emerged in Australia

International Utilisation:

COUNTRY	LEVEL OF USE		
	Trials underway	Limited use	Widely diffused
Europe		✓	
Japan		✓	

Estimated Speed and Geographic and Practitioner Use Patterns of Diffusion in the Health System

The PAS-Port system received the CE mark in Europe in March 2003 and regulatory approval in Japan in January 2004 at the time of writing. The device is not available in Australia and is not listed in the Australian Register of Therapeutic Goods.

Efficacy and Safety Issues

List of Studies Found

Total number of studies	2
Randomised controlled studies	1
Case series studies	1

The literature search identified two studies investigating both the safety and efficacy of the PAS-Port system.

In the first study, Lahtinen and colleagues conducted a prospective randomised study investigating the use of the PAS-Port device during off-pump CABG procedures in 24 patients (Lahtinen *et al.* 2006). In this study patients were randomised to receive proximal anastomosis using either the PAS-Port device (nine patients) or the conventional hand-sewn method (14 patients). In all but one case, the left internal mammary artery was anastomosed to the left descending coronary artery.

Intra-operatively, no device deployment failures were reported and the device was successfully used to create 18 proximal anastomoses. Thirty-one hand sewn anastomoses were performed and no intra-operative complications were reported. However, one case of sepsis and three cases of atrial fibrillation were reported among all patients. The method of anastomosis creation in these patients (PAS-Port or hand-sewn) was not stated.

Graft patency was evaluated at one week and 6 months post-operatively using multi-detector computed tomography scan (MDCT) of the chest. At the one week evaluation, one hand-sewn anastomosis was found to be occluded. No patency data regarding the remaining patients was presented. Additionally, signs of pulmonary embolism were detected in 3 patients in each of the two groups. However, in all but one of these patients this resolved by the 6 month follow-up. The 6 month MDCT evaluation also detected a significantly ($P = 0.04$) greater presence of complications (nature of complications not stated) in PAS-Port anastomoses recipients (14 out of 18) than in hand-sewn anastomoses recipients (11 out of 31). Proximal vein graft stenosis and vein graft occlusions were also detected at the 6 month follow up. Ten PAS-Port and 11 hand-sewn anastomoses had stenosis while four PAS-Port and two hand-sewn anastomoses were found to be occluded (difference between groups not significant). The results from this study indicated that use of the PAS-Port device was predictive of vein graft complications when adjusted for both vein graft flow (OR 8.64, 95% CI 1.66 to 45.00, $P = 0.01$) and for peripheral resistance units (OR 6.14, 95% CI 1.33 to 28.43, $P = 0.02$). Therefore, although the high rate of complications observed with the PAS-Port device suggests that the device may not be suitable as an alternative to the hand-sewn technique in the creation of proximal anastomoses, the wide 95% confidence intervals suggest larger patient numbers are required to obtain more accurate results.

Gummert *et al.* (2006) were able to demonstrate the short term and medium term safety and efficacy of PAS-Port mediated anastomosis with excellent patency results compared to the hand-sewn anastomosis performed. However, the patient cohort used not only received treatment using the PAS-Port device but also using the C-Port distal anastomosis device (Cardica Inc, Redwood City, CA, USA) making interpretation of the results difficult.

Gummert *et al.* (2006) utilised intra-operative device performance, early and 6 month angiographic graft patency and a 12 month clinical follow up assessment to evaluate the safety and efficacy of the PAS-Port system. In 54 patients, 63 PAS-Port deployment attempts were made. The majority of these (91 %) were done under on-pump conditions and the remainder under off-pump conditions. An additional 53 hand-sewn anastomoses were also performed in these patients.

Intra-operative device performance reported by the study was positive. Of the 54 deployment attempts, two attempts resulted in an incomplete anastomosis and were deemed to be unsuccessful. However, in both these occasions the anastomosis was successfully converted to a hand-sewn anastomosis.

Post-operative results were also quite positive in contrast to the study by Lahtinen and colleagues. At the time of discharge, there were 50 patients with 59 PAS-Port grafts between them (two patients died prior to discharge). Fifty-one grafts underwent early (discharge) angiographic patency evaluation (49 by angiogram and two by computed tomography) and all were found to be patent. Of 49 the grafts evaluated by angiogram, patency was rated as Fitzgibbon A (Excellent graft with unimpaired run-off) in 49/49. Early angiographic evaluation of the hand-sewn anastomosis was performed in 45 of the 53 grafts. All were evaluated by angiogram and 40 were rated as Fitzgibbon A (Excellent graft with unimpaired run-off), two as Fitzgibbon B (Narrowing of graft body greater than 50%) and three as Fitzgibbon O (Occlusion).

At the six-month patency evaluation, 52 grafts were evaluated (47 by angiography and five by CT scan). Of the 47 PAS-Port grafts evaluated by angiogram 45 (95.7%) were found to have > 50% freedom from stenosis or occlusion, one was rated Fitzgibbon B and one Fitzgibbon O. All five PAS-Port grafts evaluated by CT scan were found to be patent, giving an overall PAS-Port anastomoses patency of 98.1%. Out of 42 hand-sewn anastomoses evaluated at 6 months, 38 were rated Fitzgibbon A, one Fitzgibbon B and three Fitzgibbon O.

The 12-month clinical follow-up evaluated a total of 46 PAS-Port recipients and classified 89% as Canadian Cardiovascular Society Class 0 (Asymptomatic) or Class 1 (Angina with strenuous exercise), and 100% as New York Heart Association Class I (No limitation of activities and no symptoms during ordinary activities) or Class II (Slight, mild limitation of activity, comfortable at rest or with mild exertion). A stress electrocardiogram was also performed in 42 patients and 38 were asymptomatic, while four were found positive for myocardial ischemia.

There were no adverse events including death or bleeding associated with the use of the PAS-Port device were reported.

Ethical Issues

No issues were identified from the retrieved literature.

Cultural or Religious Considerations

No issues were identified from the retrieved literature.

Other Issues

The following contraindication for the PAS-Port device were identified in the literature retrieved (Food and Drug Administration 2005):

- Not to be used on target vessels where anastomosis would normally not be created as a result of disease
- Not to be used on target vessels with an outside diameter of less than or equal to 18 mm and with a wall thickness that would normally not be adequate for hand-sewn anastomoses
- Not to be used on graft vessels that would not normally be used in CABG procedures
- Not to be used on graft vessels with an outside diameter of less than 4 mm or more than 6 mm, or with a double wall thickness more than 1.4 mm

Recommendation:

The mix of both positive and negative results using the PAS-Port device do not give a clear indication of the potential of the device to be used as an alternative to the hand-sewn technique for proximal anastomoses. Further studies using larger patient cohorts and longer follow-up periods are required to gain a better indication of the safety and efficacy of this new technology. It is recommended that this device be monitored.

Horizon Scanning Report

Full Health Technology Assessment

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Spyder Device (Medtronic Inc., Minneapolis, MN, USA)

The Spyder device is designed to create a clampless proximal anastomosis by deploying 6 U-Clip¹ devices (Medtronic, Minneapolis, MN, USA) simultaneously within a second to create a compliant, interrupted anastomosis. The Spyder device is able to create proximal anastomoses without the requirement for a side-clamp or second manipulation of the aorta.

Stage of Development (in Australia):

- Experimental
- Investigational
- Nearly established
- Established
- Established but changed indication or modification of technique
- Should be taken out of use
- Not yet emerged in Australia

International Utilisation:

COUNTRY	LEVEL OF USE		
	Trials underway	Limited use	Widely diffused
United States		✓	

Estimated Speed and Geographic and Practitioner Use Patterns of Diffusion in the Health System

The Spyder device was cleared by the FDA in July 2003. The Spyder device is listed in the Australian Register of Therapeutic Goods.

Efficacy and Safety Issues

List of Studies Found

Total number of studies	1
Comparative studies	1

¹ The U-Clip device, by Medtronic, is an alternative to conventional sutures and surgical clips which can be used in a variety of surgical applications including anastomoses. The U-Clip is a self-closing surgical clip which eliminates the requirement for knot tying and suture management and can be easily removed if required. ARTG number: 82260, Product number: 153699.

In the only published study documenting the use of the Spyder device, Hamman *et al.* (2005) investigated the use of the Spyder device against the standard clamped technique for the creation of proximal anastomoses. The authors investigated 160 off-pump coronary artery bypass surgery cases across five centers in which a total of 250 anastomoses were created.

Intra-operative performance of the device in these patients was positive with no reported adverse events resulting from the use of the device.

Efficacy of the device was evaluated in a subset of patients in one of the five centers. In this center flow through the anastomoses was evaluated in 48 patients comparing the Spyder mediated anastomoses (32 patients) to the clamped anastomoses (16 patients). Results indicated that flow through the anastomoses in both groups was not significantly different.

Presence of emboli measured through trans-cranial Doppler signals was also evaluated in 22 patients. The results revealed that patients who had received a Spyder anastomoses (16 patients) had a tendency to record fewer Doppler signals and therefore lower emboli formation than their clamped anastomoses counterparts (6 patients). Although no statistical test was conducted due to the low numbers of patients used in this evaluation, the results suggest that use of the Spyder device during the creation of proximal anastomoses may lead to the formation of fewer emboli as the aorta does not need to be clamped.

Ethical Issues

No issues were identified from the retrieved literature.

Cultural or Religious Considerations

No issues were identified from the retrieved literature.

Other Issues

No issues were identified from the retrieved literature.

Recommendation:

There is a lack of published studies regarding the use of the Spyder device in the clinical setting. Further studies with larger patient samples are required to demonstrate the safety and efficacy of this new technology. It is recommended that this device be monitored.

Horizon Scanning Report

Full Health Technology Assessment

Monitor

Archive

Distal Anastomosis Devices

With the advent of minimally invasive coronary artery bypass procedures, the environment in which distal anastomosis procedures have been conducted in has become increasingly complex. As with proximal anastomotic devices there has been recent development in the field of distal anastomotic devices to meet this increased complexity. In this prioritising summary, three recently developed distal anastomosis devices are presented.

C-Port Distal Anastomosis System (Cardica Inc., Redwood City, CA, USA)

The C-Port Distal Anastomosis System is designed to facilitate end-to-side distal anastomosis of blood vessels during on- or off-pump coronary artery bypass (CABG) surgery (Cardica 2006). The C-Port System aims to improve outcomes in CABG patients by decreasing the time required to complete anastomoses and improving the quality and consistency of anastomoses (Cardica 2006).

Stage of Development (in Australia):

- Experimental
- Investigational
- Nearly established
- Established
- Established but changed indication or modification of technique
- Should be taken out of use
- Not yet emerged in Australia

International Utilisation:

COUNTRY	LEVEL OF USE		
	Trials underway	Limited use	Widely diffused
United States		✓	
Europe		✓	
Middle East		✓	
Canada		✓	

Despite 510(k) approval in the United States and CE mark in Europe, the paucity of studies suggest that the C-Port System is still experimental.

Estimated Speed and Geographic and Practitioner Use Patterns of Diffusion in the Health System

The United States Food and Drug Administration (FDA) granted marketing approval for the C-Port System in November 2005. The C-Port System has also been approved for marketing and distribution in Europe, the Middle East and Canada. Though it has received the CE mark, this does not give any assurance of clinical efficacy.

Efficacy and Safety Issues

In March 2006, a Horizon Scanning Prioritising Summary by the Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S) (Unpublished) was completed. The summary included one prospective multi-centre study with 130 participants and evaluated intra-operative device performance, incidence of device related adverse events, pre-discharge and 6-month angiographic graft patency and 12-month clinical outcomes for the C-Port System.

Positive results in intra-operative performance, pre-discharge and 6-month angiographic graft patency and 12-month clinical outcomes were reported in the study. In addition positive safety results were also achieved indicating that the device is a viable alternative to the hand-sewn method.

The study suggested that the C-Port System may be a safe and effective method of performing vein-to-coronary artery anastomoses, but a head-to-head comparison with hand-sewn anastomosis is needed to confirm this.

The current literature search did not reveal any new published studies documenting the use of the Cardica C-Port system.

Ethical Issues

Not applicable.

Cultural or Religious Considerations

Not applicable.

Other Issues

A new version is now available, C-Port xA, for the same intended use as the C-Port System. The new version includes modifications to improve safety and reliability as well as deployment of a greater number of staples to create leak-proof sealing without the need for additional stitches at either end of the anastomosis (Cardica 2006).

Recommendation:

Only one published case series study evaluating the safety and efficacy of the C-Port System was located. The study suggested that the C-Port System may be a safe and effective method of performing vein-to-coronary artery anastomoses, but a head-to-head comparison with hand-sewn anastomosis is needed to confirm this. It is recommended that this device be monitored.

Horizon Scanning Report

Full Health Technology Assessment

Monitor

Archive

Coronary Anastomotic Coupler (Converge Medical Inc., Sunnyvale, CA, USA)

The Coronary Anastomotic Coupler is designed to create an end-to-side 30° elliptical coronary sutureless anastomosis between the vein graft and the coronary artery.

The device is an anastomotic clip that relies on a set of concentric mating frames that clamps the vessel tissues together to create the anastomosis (Boening *et al.* 2005).

To create an anastomosis, the bypass graft (which must be at minimum 3 mm diameter) is placed over the inner frame. The outer frame is then placed over the inner tissue-covered frame, securing one end of the graft vessel between the two frames. In order to achieve a small delivery profile, a delivery tool deflects certain elements of the Coronary Anastomotic Coupler to facilitate insertion into the artery through an 8 mm long arteriotomy. Controlled release of the Coronary Anastomotic Coupler into the coronary artery lumen then causes the deflected elements to return to their original position and whilst doing this secure the end of the graft vessel against the arterial wall.

Stage of Development (in Australia):

- Experimental
- Investigational
- Nearly established
- Established
- Established but changed indication or modification of technique
- Should be taken out of use
- Not yet emerged in Australia

International Utilisation:

COUNTRY	LEVEL OF USE		
	Trials underway	Limited use	Widely diffused
Germany	✓		

Estimated Speed and Geographic and Practitioner Use Patterns of Diffusion in the Health System

The device is currently not available in Australia and is not listed in the Australian Register of Therapeutic Goods. No data regarding CE mark attainment or FDA approval was obtained.

Efficacy and Safety Issues

List of Studies Found

Total number of studies	2
Case series studies	2

The current literature search identified two published studies documenting the use of the Coronary Anastomotic Coupler.

Boening *et al.* (2005) conducted a two centre, prospective non-randomised study investigating the use of the Coronary Anastomotic Coupler in 46 patients who underwent on-pump CABG surgery. One distal anastomosis was performed using the device in each patient while the remaining anastomoses (if required) were conducted using the conventional hand-sewn method. In all cases a venous graft vessel was used to conduct the bypass.

Intra-operatively nine patients were found to be ineligible to receive a proximal anastomosis using the Coronary Artery Coupler as they did not meet all the required criteria. On three separate occasions, the removal of the device was necessitated due to the patient suffering bleeding at the site of anastomosis. In all three occasions however, the device was successfully removed and a successful conversion to a hand-sewn anastomosis was achieved. Additionally, there were four cases of anastomotic bleeding reported arising from the use of the device. On all occasions this was corrected by position change or fibrin glue. Therefore 33 patients successfully (i.e. insertion of coupler and patency of anastomosis at post-operative angiogram) received anastomoses performed using the Coronary Artery Coupler.

Angiographic evaluation of the Coronary Artery Coupler mediated anastomoses conducted at 2 months post-operatively revealed that out of the 30 coupler grafts evaluated, 29 were patent and one had stenosis of 50%. Of the hand-sewn anastomoses 30 out of 37 were found to be patent. However, direct comparison of the patency rates is not possible as the grafts performed using the device were done using graft vessels of a greater diameter than the vessels used for hand-sewn anastomoses. In addition, no standardised methods (e.g. Fitzgibbon classification) of measuring patency were used.

In a separate published paper, Klima *et al.* (2005) investigated the long-term effects of the Coronary Artery Coupler in some patients from the Boening *et al.* (2005) study. The study investigated the long term effects over a mean follow-up period of 1.8 ± 0.4 years in 15 patients.

Long-term angiographic results revealed that out of the device-mediated anastomoses and hand-sewn anastomoses two anastomoses were occluded (one in each group). The authors argue that the low incidence of anastomotic occlusion is an indication of efficacy and consistency of the Converge device. However, no standardised method of classifying patency of the anastomoses appears to have been used. The degree of patency of each

'patent' anastomoses reported in this study is therefore not known and so the true consistency of this device in making patent anastomoses cannot be determined.

Ethical Issues

No issues were identified from the retrieved literature.

Cultural or Religious Considerations

No issues were identified from the retrieved literature.

Other Issues

No issues were identified from the retrieved literature.

Recommendation:

The evidence available on the Converge Medical Coronary Anastomosis Coupler suggests that this device may be useful in the creation of distal anastomoses. However, the paucity of studies available and the lack of detail in the results reported from the available studies prompt caution. Further, more comprehensive studies regarding the safety and efficacy of the Coronary Anastomosis Coupler are required to better understand the potential risks and advantages of this new technology. It is recommended that this technology be monitored.

Horizon Scanning Report

Full Health Technology Assessment

Monitor

Archive

Magnetic Vascular Port (Ventrica Inc., Fremont, CA, USA)

The Magnetic Vascular Port (MVP) system, developed by Ventrica and distributed by Medtronic, is a system designed to create sutureless vessel anastomosis using the magnetic attraction of specially designed magnetic clips during CABG procedures.

The MVP system consists of two sets of magnetic clips (three clips per set) with each set pre-loaded into separate delivery instruments. Each set is composed of one elliptical-shaped intravascular clip and two extravascular clips. Anastomosis is achieved by first creating an anastomotic port in the graft vessel by deploying the first set of clips through a small (4 to 5 mm) incision. After the first port is created, the second port is made on the target coronary artery through a 4 to 5 mm incision. In both anastomotic ports the intravascular clip lies beneath the incised tissue while the two extravascular clips lie on either side of the intravascular clip outside the vessel. The bringing together of both ports creates an instantaneous coupling of the ports mediated by magnetic attraction creating the anastomosis.

The MVP system comes in two sizes, a 1.5 mm version (Model 6150) suitable for vessels between 1.5 and 2.0 mm internal diameter, and a 2.0 mm version (Model 6200) suitable for vessels of 2.0 to 4.0 mm internal diameter (Klima *et al.* 2004; Vico *et al.* 2005).

Stage of Development (in Australia):

- Experimental
- Investigational
- Nearly established
- Established
- Established but changed indication or modification of technique
- Should be taken out of use
- Not yet emerged in Australia

International Utilisation:

COUNTRY	LEVEL OF USE		
	Trials underway	Limited use	Widely diffused
Europe		✓	

Estimated Speed and Geographic and Practitioner Use Patterns of Diffusion in the Health System

In February 2002, the MVP system received CE mark certification in Europe allowing distribution in the continent. The device is not available in Australia and is not listed in the Australian Register of Therapeutic Goods.

Efficacy and Safety Issues

List of Studies Found

Total number of studies	4
Case series studies	4

Four studies documenting the use of the MVP system during coronary artery bypass grafting procedures were identified and retrieved. An additional study documenting the use of an earlier version of the MVP system (MVP Series 4000) was also retrieved. However, due to a substantial difference in the design of the magnetic clips used for the creation of anastomosis, data from this study is not presented.

Klima *et al.* (2004) used the second generation MVP system (MVP Series 6000) to evaluate the safety and efficacy of the device when used to create distal anastomoses during minimally invasive direct coronary artery bypass grafting (MIDCAB²) procedures. In this study, the MVP system was used in 10 out of 11 procedures to conduct anastomosis between the left internal mammary artery (LIMA) and the left anterior descending (LAD) artery. Both versions of the MVP Series 6000 device were used. In eight procedures the 2.0 mm version (Model 6200) was used while in the remaining two procedures the 1.5 mm version (model 6150) was used.

No intra-operative or post-operative complications or adverse events were reported as a result of the use of the MVP system. Although eleven patients were originally selected to undergo MIDCAB using the MVP system, one patient did not receive an MVP mediated anastomosis. In this patient, although anastomosis using the device was attempted, the graft vessel used was under significant spasm and as a result managed to dislodge the anastomotic port from the graft vessel creating a leak at the site of anastomosis. However, the anastomosis port was able to be successfully removed and a conversion to a hand-sewn anastomosis was successfully performed.

Only three patients were evaluated by angiograms to determine the patency of the anastomoses. In these patients patency was confirmed. At the 6-month follow-up, eight patients were evaluated via angiogram and in all eight, patency of the anastomosis was confirmed. Mean ischemic time was 146 (SD146) seconds thus interrupting regional coronary artery blood flow for a short amount of time, an effect which could reduce morbidity even during standard on-pump CABG procedures by reducing the time in cardiopulmonary bypass. The time required for the creation of both anastomotic ports as well as the coupling of the forms to create the anastomosis was reported at 199 (SD 191) seconds. According to the authors this is a big improvement considering that in their

² MIDCAB is a less invasive approach to beating heart surgery indicated for use when bypassing only one or two coronary arteries.

experience hand-sewn anastomoses take between 360 and 900 seconds to create. In addition the shorter times may also help reduce ischemia related complications.

This study, although small in size demonstrated the advantage of using the MVP system to create anastomosis in terms of time required to create one. However, the context in which this device was used (i.e. MIDCAB procedures) may not allow for the generalisation of results into conventional on- and off-pump CABG procedures. In addition larger patient numbers and a standardised method of patency evaluation (such as Fitzgibbon classification) is required to further support the observations reported in this study.

Vicol and colleagues used the MVP system to perform 18 distal anastomoses in eleven patients on patients undergoing on-pump CABG) (Vicol *et al.* 2005). In order to demonstrate the versatility of this new device, the investigators utilised a variety of graft vessels and target arteries as follows:

Graft vessels:	No. of patients
Left internal thoracic artery	9
Saphenous vein	6
Right internal thoracic artery	2
Radial artery	1
Target arteries:	
Left anterior descending	9
Marginal branch	4
First diagonal branch	3
Right coronary artery	2

Of the 18 anastomoses created, 15 were performed in an end-to-side fashion and three were performed in a side-to-side fashion. A further seven hand-sewn anastomoses (due to inadequate target arteries) were also performed in these eleven patients for a total of 25 anastomoses.

Intra-operative performance of the MVP system was comparable to Klima *et al.* (2004) with no major complications reported. One conversion to a hand-sewn anastomosis was required as a result of the vessel wall being too thick for the device to function properly. In another two cases problems with the magnetic clips during the creation of the anastomotic ports led to an unsuccessful initial attempt. However, both were followed by successful second attempts. In all cases intra-operative hemostasis and patency (through transit time flow measurement) was observed. One case of post-operative bleeding was reported requiring re-operation, however, this was not a result of the use of the MVP device.

The time for anastomosis with the MVP device stated was 13 (SD 2.9) minutes. However, no definition of 'time for MVP anastomosis' was given so this result cannot be compared directly with Klima *et al.* (2004).

Angiographic evaluation of patency was performed in ten cases prior to discharge demonstrating the patency of the MVP anastomosis and hand-sewn anastomoses. However, no follow up examination was reported, therefore the status of the patients and the anastomoses beyond discharge is not known. Furthermore, this study did not use a standardised system to classify patency when it was evaluated so the degree of patency in the pre-discharge evaluation is unknown (Klima *et al.* 2004).

In the first of two studies by Athanasiou and colleagues, the MVP system was used in 12 patients undergoing both on-pump (three patients) and off-pump (nine patients) CABG procedures (Athanasiou *et al.* 2004). In a similar fashion to previous studies the versatility of the MVP system was demonstrated. In this case however, the device was used to create both distal and proximal anastomoses. Twelve left internal thoracic artery to left anterior descending coronary anastomoses and two radial artery Y-grafts from the left internal thoracic artery to the circumflex territories were performed.

No deaths or device related injuries were reported for both types of anastomoses. Angiographic evaluation of patency was evaluated in only three patients who underwent on-pump distal anastomoses. All anastomoses were fully patent. Despite little data being presented, this study demonstrated the ability of the MVP system to create proximal anastomoses.

In a second study, Athanasiou *et al.* used the MVP device to create proximal anastomoses as part of clampless off-pump coronary artery bypass procedures (Athanasiou *et al.* 2006). Though not specifically indicated to perform proximal anastomoses, the MVP system was nonetheless used create anastomoses of the radial artery (n = 8) or right internal thoracic artery (n = 1) graft as a Y-graft from the left internal thoracic artery to the circumflex territories.

One death was reported, however, this was not related to the use of the device. Two patients initially considered suitable to receive MVP mediated anastomoses were successfully converted to hand-sewn anastomosis because the anastomoses created were deemed to be unsuitable. Throughout the follow-up period of 7 (SD 1.8) months no major adverse events were reported (Athanasiou *et al.* 2006).

Multi-detector row computed tomography coronary angiograms (time of evaluation not stated) of five patients showed that in each of these patients all anastomoses were patent. However, as in other studies, no standardized method of classifying patency was used. Health related quality of life assessment using the SF-36 questionnaire showed a significant improvement at the 6-month follow-up in the physical functioning (P = 0.01) and general health (P = 0.02) sub-scores (Athanasiou *et al.* 2006).

Athanasidou *et al.* (2006) have further demonstrated in this study the versatility of the MVP system. Although no reason for using the MVP system for creating proximal anastomoses was given, the authors have demonstrated a potential new indication for this anastomotic device.

Ethical Issues

No issues were identified from the retrieved literature.

Cultural or Religious Considerations

No issues were identified from the retrieved literature.

Other Issues

One possible contraindication was identified in the literature retrieved. Athanasidou *et al.* (2006) note that a relative contraindication to the use of the MVP device is a history of neurological or spinal disease which may require magnetic imaging. The authors suggest that magnetic imaging has the potential to disrupt any distal anastomoses created using the device.

Recommendation:

The MVP system has been shown in clinical studies to be a safe option in the creation of distal anastomoses. In addition its flexibility in terms of vessels capable of being used with the device has been demonstrated. The device may also be used for proximal anastomoses, though data regarding this use of the device is limited. Further studies documenting the long term clinical (specifically patency) outcomes of recipients of MVP mediated anastomoses are required to ensure effectiveness of the device. It is recommended the device be monitored.

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| <input type="checkbox"/> Horizon Scanning Report | <input type="checkbox"/> Full Health Technology Assessment |
| <input checked="" type="checkbox"/> Monitor | <input type="checkbox"/> Archive |

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Search Criteria:

A search of MEDLINE, PubMed, *The Cochrane Library*, the Current Controlled Trials metaRegister, the UK National Research Register, International Network of Agencies for Health Technology Assessment, relevant online journals and the Internet was conducted in February 2006.

Search terms used were: 'PAS-Port', 'Enclose', 'Enclose II', 'Spyder', 'Coronary Anastomotic Coupler', 'CAC', 'Magnetic Vascular Port', 'Magnetic Vascular Positioner', 'MVP', 'MVP system', 'C-Port', 'distal anastomosis system', 'Cardica', 'Converge Medical', 'Ventrica', 'proximal anastomosis', 'distal anastomosis', 'bypass surgery' and 'anastomosis', 'manual anastomotic', 'automatic anastomosis', 'automated anastomosis'.

This Horizon Scanning Prioritising Summary was prepared by Mr Luis Zamora from the NET-S Project, ASERNIP-S for the Health Policy Advisory Committee on Technology (Health PACT), on behalf of the Medical Services Advisory Committee (MSAC) and the Australian Health Ministers' Advisory Council (AHMAC).